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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/019,441	02/05/1998	MITCHELL E. REFF	012712-502	2038

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EXAMINER
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HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/22/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/019,441	REFF ET AL.
	Examiner "Neon" Phuong Huynh	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 April 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 42-60 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 42-60 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The request filed on 4/24/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/019,441 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 42-60 are pending and being acted upon in this application.
3. The rejection of Claims 1-2, 4-5, 8-15, 17-18 and 21-25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 09/929,053 is hereby withdrawn in view of the cancellation of claims 1-2, 4-5, 8-15, 17-18 and 21-25.
4. Applicant should amend the first line of the specification to update the relationship between the instant application and 08/803,085, filed 2/20/1997, which is now Pat No. 6,011,138.
5. Claim 49 is objected to because “colon” in claim 49, line 4 should have been “codon”.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 42-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a chimeric anti-human CD23 antibody wherein the variable light chain “consisting of” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “consisting of” the polypeptide encoded by SEQ ID NO: 2, and a human constant region selected from the group consisting of human gamma-1 and human gamma3 constant region, (2) a composition comprising an anti-human CD23 antibody mentioned above and a pharmaceutically acceptable carrier, (3) a chimeric anti-human CD23 antibody wherein the variable light domain “consisting of” the polypeptide encoded by SEQ I DNO: 3, the variable heavy domain consisting of the polypeptide encoded by SEQ ID NO: 4 and a human constant region selected from the group consisting of a human gamma-1 constant region and a human gamma-3 constant region, (4)

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a chimeric anti-human CD23 antibody wherein the variable light domain consisting of the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "consisting of" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine, (5) a composition comprising a chimeric anti-human CD23 antibody wherein the variable light domain "consisting of" the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain consisting of the polypeptide encoded by SEQ ID NO: 4 and a human constant region selected from the group consisting of a human gamma-1 constant region and a human gamma-3 constant region and a pharmaceutical acceptable carrier, (6) a composition comprising a chimeric anti-human CD23 antibody wherein the variable light domain consisting of the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "consisting of" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine and a pharmaceutical acceptable carrier, (7) a composition comprising an anti-human CD23 antibody a chimeric anti-human CD23 antibody wherein the variable light domain "consisting of" the polypeptide encoded by SEQ I DNO: 3, the variable heavy domain consisting of the polypeptide encoded by SE QI DNO: 4, a human gamma-1 constant region and a pharmaceutical acceptable carrier, (8) a composition comprising an anti-human CD23 antibody a chimeric anti-human CD23 antibody wherein the variable light domain "consisting of" the polypeptide encoded by SEQ I DNO: 3, the variable heavy domain consisting of the polypeptide encoded by SE QI DNO: 4, a human gamma-3 constant region and a pharmaceutical acceptable carrier, (9) a composition comprising a chimeric anti-human CD23 antibody wherein the variable light domain consisting of the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "consisting of" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine, a human gamma-1 constant region and a pharmaceutical acceptable carrier, and (10) a composition comprising a chimeric anti-human CD23 antibody wherein the variable light domain consisting of the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "consisting of" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine, a human gamma-3 constant region and a pharmaceutical acceptable carrier for inhibiting IL-4 induced IgE production in vitro, **does not reasonably provide enablement for (1) any chimeric anti-human CD23 antibody wherein the variable light chain "comprises" the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain "comprises" the polypeptide encoded by SEQ ID NO: 2, and "comprising" a human constant region selected**

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from the group consisting of human gamma-1 and human gamma3 constant region, (2) *any* chimeric anti-human CD23 antibody wherein the variable light chain “comprises” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 2, and “comprising” a human constant region wherein the human constant region is a human gamma-1 constant region, (3) *any* chimeric anti-human CD23 antibody wherein the variable light chain “comprises” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 2, and “comprising” a human constant region wherein the human constant region is a human gamma-3 constant region, (4) *any* pharmaceutical composition containing *any* chimeric anti-human CD23 antibody wherein the variable light chain “comprises” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 2, and “comprising” a human constant region selected from the group consisting of human gamma-1 and human gamma-3 constant region and a pharmaceutically acceptable carrier, (5) *any* pharmaceutical composition containing *any* chimeric anti-human CD23 antibody wherein the variable light chain “comprises” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 2, and “comprising” a human constant region wherein the human constant region is a human gamma-1 constant region, and a pharmaceutically acceptable carrier, (6) **any pharmaceutical composition** containing *any* chimeric anti-human CD23 antibody mentioned above, (7) *any* chimeric anti-human CD23 antibody wherein the variable light domain “comprises” the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain “comprises” the polypeptide encoded by SEQ I DNO: 4 and a human constant region selected from the group consisting of a human gamma-1 constant region and a human gamma-3 constant region, (8) *any* chimeric anti-human CD23 antibody wherein the variable light domain “comprises” the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine, (9) *any* chimeric anti-human CD23 antibody wherein the variable light domain “comprises” the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain “comprises” the polypeptide encoded by SEQ I DNO: 4 and a human constant region which “comprises” human gamma-1 constant region, (10) *any* chimeric anti-human CD23 antibody wherein the variable light domain “comprises” the polypeptide encoded by SEQ I DNO: 3, the variable heavy domain “comprises” the polypeptide encoded by SEQ I DNO: 4 and a human constant region which “comprises” human gamma-3 constant

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region, (11) *any* chimeric anti-human CD23 antibody wherein the variable light domain “comprises” the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain “comprises” the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine “which comprises” a human gamma-3 constant region, and (12) *any* pharmaceutical composition comprising any anti-human CD23 antibody mentioned above for treating *any* diseases such as autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only five murine anti-human CD23 monoclonal antibodies (5E8, 6G5, 2C8, B3B11 and 3G12) and six primate anti-human CD23 monoclonal antibodies (P5E8G4P, p5E8G1PN, p5E8G1, p5E8G1N, p6G5G1 and p6G5G4P) and these primatized antibodies contain human gamma-1 or human gamma-4 constant regions for inhibiting IgE production in vitro.

The specification does not provide sufficient guidance and working examples to enable one skilled in the art to make and use *any* chimeric anti-human CD23 antibody mentioned above that has the functional capacity to inhibit IgE, much less for treating any disease. The term “comprises” or “comprising” is open-ended. It expands the variable light chain domain, the variable heavy chain domain and the constant region, which are all fragments of the chimeric anti-human CD23 antibody, to include additional amino acid at either or both ends, and the corresponding polynucleotide encoding the additional amino acids. Without the specific amino acid residues (structure) and the corresponding polynucleotide, one skilled in the art would not be able to add such that the resulting antibody would still bind human CD23 and block IgE. It is well known in the art that a nucleic acid sequence is not sufficient to know the structure and/or function of the protein encoded by said nucleic acid sequence. It is well known in the art that a

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nucleic acid sequence is not sufficient to know the structure and/or function of the protein encoded by said nucleic acid sequence.

Skolnick *et al* teach that determining the sequence of a nucleic acid molecule does not provide sufficient information to obtain the structure of the protein. Further, the function of a protein cannot be determined simply by knowing the structure of a protein, as many proteins are multifunctional. Changes in nucleic acid sequence can, therefore, potentially result in changes in essential three-dimensional structures of the given protein, and consequently, it's function.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Given the indefinite number of undisclosed amino acid and the corresponding polynucleotide, it is unpredictable which undisclosed variable light chain, variable heavy chain domain and constant domain will have the same binding specificity and function as the chimeric anti-human CD23 antibody such as p5E8G1, p5E8G1N, and p6G5G1, in turn, would be useful for *any* purpose. Since the variable light chain and heavy chain domains are not enabled, the binding specificity of the claimed chimeric anti-human CD23 antibody is not enabled. It follows that the pharmaceutical composition comprising any chimeric anti-human CD23 is not enabled. Further, there is insufficient guidance as to the specific disease such as autoimmune disease could be treated using any chimeric anti-human CD23 antibody mentioned above.

Van Noort *et al* teach autoimmune diseases can be species and model-dependent (See entire document, pages 167-168, in particular). Given the indefinite number of undisclosed inflammatory autoimmune disease, it is unpredictable which undisclosed chimeric anti-human CD23 antibody would be useful for treating any autoimmune disease. Further, the Merck manual does not recognize the use of *any* chimeric anti-human CD23 for treating *any* inflammatory autoimmune disease such as rheumatoid arthritis (See page 420-421, in particular). Even if the chimeric anti-human CD23 antibody is use for inhibiting the production of IgE induced by IL-4, the in vivo data as shown in Figures 9 and 10 are not significantly different than the control (See error bars).

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

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In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

8. Claims 42-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) *any* chimeric anti-human CD23 antibody wherein the variable light chain “**comprises**” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “**comprises**” the polypeptide encoded by SEQ ID NO: 2, and “**comprising**” a human constant region selected from the group consisting of human gamma-1 and human gamma3 constant region, (2) *any* chimeric anti-human CD23 antibody wherein the variable light chain “**comprises**” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “**comprises**” the polypeptide encoded by SEQ ID NO: 2, and “**comprising**” a human constant region wherein the human constant region is a human gamma-1 constant region, (3) *any* chimeric anti-human CD23 antibody wherein the variable light chain “**comprises**” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “**comprises**” the polypeptide encoded by SEQ ID NO: 2, and “**comprising**” a human constant region wherein the human constant region is a human gamma-3 constant region, (4) *any* pharmaceutical composition containing *any* chimeric anti-human CD23 antibody wherein the variable light chain “**comprises**” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “**comprises**” the polypeptide encoded by SEQ ID NO: 2, and “**comprising**” a human constant region selected from the group consisting of human gamma-1 and human gamma-3 constant region and a pharmaceutically acceptable carrier, (5) *any* pharmaceutical composition containing *any* chimeric anti-human CD23 antibody wherein the variable light chain “**comprises**” the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain “**comprises**” the polypeptide encoded by SEQ ID NO: 2, and “**comprising**” a human constant region wherein the human constant region is a human gamma-1 constant region, and a pharmaceutically acceptable carrier, (6) *any*

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**pharmaceutical composition** containing *any* chimeric anti-human CD23 antibody mentioned above, (7) *any* chimeric anti-human CD23 antibody wherein the variable light domain "comprises" the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ I DNO: 4 and a human constant region selected from the group consisting of a human gamma-1 constant region and a human gamma-3 constant region, (8) *any* chimeric anti-human CD23 antibody wherein the variable light domain "comprises" the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine, (9) *any* chimeric anti-human CD23 antibody wherein the variable light domain "comprises" the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ I DNO: 4 and a human constant region which "comprises" human gamma-1 constant region, (10) *any* chimeric anti-human CD23 antibody wherein the variable light domain "comprises" the polypeptide encoded by SEQ I DNO: 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ I DNO: 4 and a human constant region which "comprises" human gamma-3 constant region, (11) *any* chimeric anti-human CD23 antibody wherein the variable light domain "comprises" the polypeptide encoded by SEQ ID NO: 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines codon at position 75 is replaced with a lysine "which comprises" a human gamma-3 constant region, and (12) *any* pharmaceutical composition comprising any anti-human CD23 antibody mentioned above for treating *any* diseases such as autoimmune diseases.

The specification discloses only five murine anti-human CD23 monoclonal antibodies (5E8, 6G5, 2C8, B3B11 and 3G12) and six primate anti-human CD23 monoclonal antibodies (P5E8G4P, p5E8G1PN, p5E8G1, p5E8G1N, p6G5G1 and p6G5G4P) and these primatized antibodies contain human gamma-1 or human gamma-4 constant regions for inhibiting IgE production in vitro.

With the exception of the specific a chimeric anti-human CD23 antibody, there is insufficient written description about the structure associated with function of *any* chimeric anti-human CD23 antibody wherein the variable light chain "comprises" the polypeptide encoded by SEQ ID NO: 1 or 3, the variable heavy domain "comprises" the polypeptide encoded by SEQ ID NO: 2 or 4, and "comprising" a human constant region selected from the group consisting of human gamma-1 and human gamma3 constant region. The term "comprises" or "comprising" is

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open-ended. It expands the variable light chain domain, the variable heavy chain domain and the constant region, which are all fragments of the chimeric anti-human CD23 antibody, to include additional amino acid at either or both ends, and the corresponding polynucleotide encoding the additional amino acids. Further, the specification disclosed only six chimeric anti-human CD23 antibodies. Given the lack of a written description of *any* pharmaceutical composition comprising *any* chimeric anti-human CD23 for treating *any* disease, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
10. Claims 49 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "which comprises a human gamma-3 constant region" in claim 53 has no antecedent basis in base claim 49. Base claim 49 recites a chimeric anti-human CD23 antibody wherein the variable light domain comprises the polypeptide encoded by SEQ ID NO: 3 and the variable heavy domain comprises the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagines colon at position 75. The recitation of "which comprises a human gamma-3 constant region" in claim 53 has no antecedent basis in base claim 49 because the term "which" refers to the variable heavy domain in claim 49 and the variable domain of the heavy chain is not the same as the human gamm-3 constant region.

The recitation of "asparagines colon at position 75" in claim 49 is ambiguous. One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention. The term "colon" should have been "codon". Further, the "position 75" refers to the position within the polypeptide encoding by SEQ ID NO: 4 and not the position within the polynucleotide of SEQ ID NO: 4. The term "codon" refers to the triplet nucleotide that encodes the specific amino acid residue(s). Appropriate correction is required.

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11. Claims 42-60 appear to be free of prior art.
12. No claim is allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
14. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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